

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

KONINKLIJKE PHILIPS N.V. and)	
IP2IPO INNOVATIONS, LTD.,)	
)	
Plaintiffs,)	
)	C.A. No. 24-206-CFC
v.)	
)	JURY TRIAL DEMANDED
OPSENS INC., OPSSENS MEDICAL,)	
OPSENS MEDICAL INC., and)	
HAEMONETICS CORPORATION,)	
)	
Defendants.)	

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants OpSens Inc., OpSens Medical, OpSens Medical Inc., and Haemonetics Corporation (collectively, “Defendants”) by and through the undersigned counsel, hereby answer and assert defenses (“Answer”) to the Complaint filed on February 15, 2024 (“Complaint,” D.I. 1) by Plaintiffs Koninklijke Philips N.V. and IP2IPO Innovations, Ltd. (collectively, “Plaintiffs”).

NATURE OF THE ACTION

1. Defendants deny that they infringe, or have ever infringed, U.S. Patent No. 10,912,463 (the “463 Patent”).

2. Defendants lack sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 2 of the Complaint, and therefore, deny them.

PARTIES

3. Defendants lack sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint, and therefore, deny them.

4. Defendants lack sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 4 of the Complaint, and therefore, deny them.

5. Defendants lack sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 5 of the Complaint, and therefore, deny them.

6. Defendants admit that OpSens, Inc. is a corporation duly organized and existing under the laws of Quebec, Canada and is located at 750 Bd. Du Parc Technologique, Quebec, QC, G1P 4S3, Canada. Defendants further admit that OpSens, Inc. is a wholly-owned subsidiary of Haemonetics Corporation.

7. Defendants admit that, as of the time of filing of the Complaint, OpSens Inc. sells and markets interventional cardiology or PCI devices throughout the United States, including the State of Delaware. Defendants deny that OpSens Inc. manufactures interventional cardiology or PCI devices in the United States.

8. Defendants deny the allegations contained in Paragraph 8 of the Complaint. Defendant OpSens Medical is the same entity as Defendant OpSens Medical Inc.

9. Defendants deny the allegations contained in Paragraph 9 of the Complaint. Defendant OpSens Medical is the same entity as Defendant OpSens Medical Inc.

10. Defendants admit that OpSens Medical Inc. is a corporation duly organized and existing under the laws of the State of Delaware with a registered agent, Corporation Trust Company, located at 251 Little Falls Drive, Wilmington, DE, 19808, USA.

11. Defendants admit that, as of the time of filing of the Complaint, OpSens Medical Inc. sells and markets interventional cardiology or PCI devices throughout the United States, including the State of Delaware. Defendants deny the remaining allegations contained in Paragraph 11 of the Complaint.

12. Defendants admit that Haemonetics Corporation is a corporation duly organized and existing under the laws of the state of Massachusetts, with a registered agent, Corporation Trust Company, located at 1209 Orange Street, Wilmington, DE, 19801, USA.

13. Defendants admits that, as of the time of filing of the Complaint, Haemonetics sells and markets interventional cardiology or PCI devices throughout

the United States, including the State of Delaware. Defendants deny the remaining allegations contained in Paragraph 13 of the Complaint.

THE ASSERTED PATENT

U.S. Patent 10,912,463

14. Defendants admit that, based on the face of the '463 Patent, it appears to be entitled "Devices, Systems, and Methods for Assessing a Vessel." Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the remaining allegations in Paragraph 14 of the Complaint, and, therefore, deny them.

15. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the allegations in Paragraph 15 of the Complaint, and, therefore, deny them.

JURISDICTION AND VENUE

16. Defendants incorporate by reference their responses to the prior paragraphs of the Complaint as if fully set forth herein.

17. Defendants admit that the Complaint purports to allege claims for patent infringement and that the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Defendants specifically deny that they infringe, or have ever infringed, the '463 Patent.

18. Defendant OpSens Inc. does not dispute that it is subject to the Court's personal jurisdiction. Defendant OpSens Inc. does dispute and specifically denies

any and all allegations of patent infringement. Defendants deny the remaining allegations in Paragraph 18 of the Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of the Complaint. Defendant OpSens Medical is the same entity as Defendant OpSens Medical Inc.

20. Defendant OpSens Medical Inc. does not dispute that it is subject to the Court's personal jurisdiction. Defendant OpSens Medical Inc. does dispute and specifically denies any and all allegations of patent infringement. Defendants deny the remaining allegations in Paragraph 20 of the Complaint.

21. Defendant Haemonetics Corporation does not dispute that it is subject to the Court's personal jurisdiction. Defendant Haemonetics Corporation does dispute and specifically denies any and all allegations of patent infringement. Defendants deny the remaining allegations in Paragraph 21 of the Complaint.

22. Defendants deny that they maintain regular and established places of business in Delaware, but admit one defendant is incorporated in the State of Delaware. Defendants do not dispute that venue is proper but do dispute and specifically deny any and all allegations of patent infringement.

FACTS

23. Defendants incorporate by reference their responses to the prior paragraphs of the Complaint as if fully set forth herein.

24. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint and, therefore, deny them.

25. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 of the Complaint and, therefore, deny them.

26. Defendants admit that patients with heart problems have been assessed using a “Fractional Flow Reserve” or “FFR” procedure. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 26 of the Complaint and, therefore, deny them.

27. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of the Complaint and, therefore, deny them.

28. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint and, therefore, deny them.

29. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint and, therefore, deny them. The paper referenced in Paragraph 29 of the Complaint speaks for itself.

30. Defendants admit that they market their “dPR” ratio. Defendants deny the remaining allegations in Paragraph 30 of the Complaint. Exhibit B as referenced in Paragraph 30 of the Complaint speaks for itself.

31. Exhibit C as referenced in Paragraph 31 of the Complaint speaks for itself. Defendants deny any remaining allegations in Paragraph 31 of the Complaint.

32. Defendants specifically deny that they infringe, or have infringed, the ’463 Patent. Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the remaining allegations in Paragraph 32 of the Complaint, and, therefore, deny them.

THE ACCUSED PRODUCTS

33. Defendants incorporate by reference their responses to the prior paragraphs of the Complaint as if fully set forth herein.

34. Paragraph 34 of the Complaint does not contain factual allegations to which a response is required. If a response is deemed required, Defendants deny that they infringe, or have infringed, the ’463 Patent and Defendants lack sufficient information or knowledge to form a belief as to the truth or falsity of the remaining allegations in Paragraph 34 of the Complaint, and therefore, deny them.

35. The referenced website in Paragraph 35 of the Complaint speaks for itself. Defendants admit that the quotations and image within Paragraph 35 of the

Complaint appear to come from the cited website. Defendants deny the remaining allegations of Paragraph 35 of the Complaint, if any.

36. The referenced website in Paragraph 36 of the Complaint speaks for itself. Defendants admit that the quotations and image within Paragraph 36 of the Complaint appear to come from the cited website. Defendants deny the remaining allegations of Paragraph 36 of the Complaint, if any.

37. Defendants deny that they infringe, or have infringed, the '463 Patent. The referenced website in Paragraph 37 of the Complaint speaks for itself. Defendants admit that the quotations and image within Paragraph 37 of the Complaint appear to come from the cited website. Defendants deny the remaining allegations of Paragraph 37 of the Complaint, if any.

38. Defendants deny the allegations in Paragraph 38 of the Complaint.

CLAIM FOR RELIEF

Patent Infringement of the '463 Patent under 35 U.S.C. § 271¹

39. Defendants incorporate by reference their responses to the prior paragraphs of the Complaint as if fully set forth herein.

¹ Defendants have reproduced the headings and subheadings used in Plaintiffs' Complaint in Defendants' Answer for convenience. To the extent any headings or subheadings can be construed as a factual allegation, Defendants deny those allegations. Defendants also specifically deny they infringe, or have infringed, the '463 Patent.

40. Defendants deny the allegations in Paragraph 40 of the Complaint.

41. Paragraph 41 of the Complaint does not include factual allegations to which a response is required. To the extent a response is deemed required, Defendants deny the allegations in Paragraph 41 of the Complaint, including any and all allegations of infringement included within Exhibit D. Defendants specifically deny that they infringe, or have infringed, the '463 Patent.

42. Defendants deny the allegations in Paragraph 42 of the Complaint.

43. Defendants deny the allegations in Paragraph 43 of the Complaint.

PRAYER FOR RELIEF

Defendants incorporate by reference all preceding paragraphs of this Answer as if fully set forth herein. Defendants deny any and all allegations of patent infringement in the Complaint. Defendants specifically deny that Plaintiffs are entitled to any relief requested in paragraphs “A-G” of the Complaint’s Prayer for Relief, or any other relief.

DEMAND FOR JURY TRIAL

Plaintiffs’ demand for a jury trial does not require a response.

DEFENDANTS’ ADDITIONAL DEFENSES

Pursuant to Federal Rule of Civil Procedure 8(c), and without altering any applicable burdens of proof, Defendants assert the following additional defenses to the Complaint. Defendants also reserve the right to amend or supplement these defenses as additional facts become known.

FIRST DEFENSE: FAILURE TO STATE A CLAIM

The Complaint fails to state a cause of action against Defendants for which relief can be granted.

SECOND DEFENSE: NON-INFRINGEMENT

Defendants have not infringed, and currently do not infringe, any valid claim of the '463 Patent, literally or under the doctrine of equivalents, directly, indirectly, contributorily, or by inducement and are not liable for any infringement. Defendants do not infringe numerous limitations within the asserted claims.

For example, Defendants independently developed the Accused Products, including their own solution as to how to calculate a distal pressure ratio which is used to evaluate the stenosis of a patient's vessel. Defendants' distal pressure ratio calculation is performed in a different manner than that claimed in the '463 Patent. For example, the Accused Products (as spelled out in Paragraph 34 of the Complaint) do not infringe the following claim limitations:

- “output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient” (Ex. A to the Complaint, cl. 1);
- “wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window

divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window” (Ex. A to the Complaint, cl. 1);

- “wherein the pressure ratio is calculated as an average of the received distal pressure measurements obtained during the diagnostic window divided by an average of the received proximal pressure measurements obtained during the diagnostic window” (Ex. A to the Complaint, cl. 11);
- “output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient” (Ex. A to the Complaint, cl. 11);
- “wherein the pressure ratio is calculated as an average of the plurality of the distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window” (Ex. A to the Complaint, cl. 26);
- “output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel

without a hyperemic physiological effect on the patient” (Ex. A to the Complaint, cl. 26).

Defendants have additional non-infringement positions and reserve their rights to present those positions at the appropriate time.

THIRD DEFENSE: INVALIDITY

One or more claims of the '463 Patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35, U.S.C., or the rules, regulations, and laws related thereto, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTH DEFENSE: PROSECUTION HISTORY ESTOPPEL

The relief sought by Plaintiffs is barred, in whole or in part, under the doctrine of prosecution history estoppel due to amendments and/or statements made during prosecution of the patent-in-suit.

FIFTH DEFENSE: UNAVAILABILITY OF INJUNCTIVE RELIEF

Plaintiffs are not entitled to injunctive relief, as a matter of law, and cannot satisfy the requirements applicable to injunctive relief in any form.

SIXTH DEFENSE: LIMITATION ON DAMAGES AND FAILURE TO MARK

Plaintiffs' claim for damages is barred, in whole or in part, by 35 U.S.C. §§ 286 or 287. To the extent any claim of the patents-in-suit is invalid, Plaintiffs are also barred from recovering costs by 35 U.S.C. § 288.

SEVENTH DEFENSE: GOOD FAITH

Defendants have engaged in all relevant activities in good faith, thereby precluding Plaintiffs, even if they prevail, from recovering reasonable attorneys' fees or costs under 35 U.S.C. § 285.

EIGHTH DEFENSE: UNENFORCEABILITY

The claims of the '463 Patent are unenforceable due to prosecution laches and/or inequitable conduct.

RESERVATION OF ADDITIONAL DEFENSES

Defendants reserve the right to assert additional defenses in the event that discovery or other analysis indicates that additional defenses are appropriate.

DEFENDANTS' PRAYER FOR RELIEF

WHEREFORE, Defendants pray this Court enter judgment:

- A. A judgment in favor of Defendants and denying Plaintiffs all relief requested in their Complaint and dismissing the Complaint with prejudice;
- B. A judgment against Plaintiffs finding that Defendants have not and do not infringe and are not liable for any infringement of any valid and enforceable claim of the '463 Patent;
- C. A judgment against Plaintiffs finding that one or more claims of the '463 Patent are patent ineligible and/or invalid;
- D. A judgment that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding Defendants their reasonable attorneys' fees;

- E. An award of costs to Defendants; and
- F. Such other relief as the Court shall deem just and proper.

JURY DEMAND

Defendants demand a trial by jury on all triable issues.

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Dated: August 12, 2024